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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/314,919	05/19/1999	WILLY MICHEL	6464	5806
25763	7590	11/25/2002	EXAMINER	
DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT 50 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402-1498			MENDEZ, MANUEL A	
		ART UNIT	PAPER NUMBER	
		3763	19	
DATE MAILED: 11/25/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/314,919	MICHEL ET AL.
	Examiner Manuel Mendez	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 10,12-17,21-24 and 27-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 10,12-17,21-24 and 27-62 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>18</u> .	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**Claims 10, 11, 12, 13, 16, 17, and 21-24** are rejected under 35 U.S.C. 102(e) as being anticipated by **Bestetti, et al.<sup>1</sup>, Baudino, or Schafer, et al.** The cited references disclose an access means with an elastic self-closing diaphragm for accessing the interior of the body; the access means is implantable in the body and adapted to allow access to the body fluids through the diaphragm. Concerning method claims 16 and 17, the cited references disclose structures capable of performing the functions disclosed by the claim. In relation to claims 21-24, Bestetti, et al., and Schafer, et al., disclose anchors implanted in or under the skin.

**Claims 10, 12, 13, 15, 16, 27, 40, and 54** are rejected under 35 U.S.C. 102(b) as being anticipated by **Donaldson, et al.** The cited patent discloses an elastic self-closing diaphragm, a feed element associated with the self-closing diaphragm, the feed element being suitable for delivery of a substance into a subject; and an aspiration element associated with the self-closing diaphragm, the aspiration element having a second distal end disposed opposite the elastic self closing diaphragm, wherein the aspiration element is suitable for accessing subject fluids. Please refer to figure 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 28-39, 41-53, and 55-62** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Schafer, et al., in view of Bestetti, et al.<sup>2</sup>, Donaldson, et al., and Patsalos, et al.** The Schafer, et al., patent discloses an access means with an elastic self-closing diaphragm for accessing the interior of the body; the access means is implantable in the body and adapted to allow access to the body fluids through the diaphragm. The Schafer, et al., patent does not disclose a multi-lumen structure or the use of sensors in combination with the device for fluid analysis. However, the above enhancements disclosed by the claims in question are conventional in the art as evidenced by the teachings of **Bestetti, et al., Donaldson, et al., and Patsalos, et al.**

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<sup>1</sup> U.S. Patent Number 6,270,475.

The Bestetti, et al., patent shows in figure 1, the use of wings to provide more stability to the access port; Donaldson, et al., shows in figure 3, an access port having two lumens, one for the infusion of fluids into the body and another for the aspiration of substances from the body; and the Patsalos, et al., patent shows in figure 10, a sensor or probe use in combination with an access port.

Accordingly, in view of the conventionality of the enhancements, it would have been obvious for a person of ordinary skill in the art to modify Schafer, et al., to include the limitations disclosed in the claims in question. Conclusively, these limitations are considered obvious design alternatives.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.



Manuel Mendez  
Primary Examiner  
Art Unit 3763